Rocket Medical plc - 510(k) Notification
Embryon® Ultrasound Needle Guide
AUG - 8 2003

K032015

Summary of Safety and Effectiveness

This is a class II device, registered by Rocket Medical plc (Establishment number: 8010022/9610632). This device is substantially equivalent to medical devices which are currently in commerce and have been submitted to the FDA

Re-usable ultrasound needle guides have been in use for over 20 years. The device is safe and effective for the application for which it is intended. More recently concerns about cross infection and patient pain have produced some single use versions being in use for the past 3 years, without any known incident in the UK.

Rocket Medical plc continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION

I hereby certify that this Summary of Safety and Effectiveness applies for the above indicated device.

20/6/03
Date

T. Charlton
Signed by Tracy Charlton
Regulatory Affairs Manager
Rocket Medical plc
Wear Industrial Estate, Washington
Tyne & Wear, England. NE38 9BZ

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Tracy Charlton
Regulatory Affairs Manager
Rocket Medical PLC
Wear Industrial Estate
District 6, Washington
Tyne & Wear, NE38 9BZ
UNITED KINGDOM

Re: K032015
Trade/Device Name: Embryon® Ultrasound Needle Guide
Regulation Number: 21 CFR 884.6100
Regulation Name: Assisted reproduction needles
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed imaging system
Regulatory Class: II
Product Code: 85 MQE and 90 IYO
Dated: June 20, 2003
Received: July 21, 2003

Dear Ms. Charlton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Rocket Medical plc - 510(k) Notification
Embryon® Ultrasound Needle Guide

Indications for Use

Ultrasound Needle Guides are for the attachment of needles to specified ultrasound transducers.

For use in ultrasound guided oocyte harvesting and tissue biopsy.

T.Charlton

Signed T.Charlton
Regulatory Affairs Manager

Rocket Medical Plc
20th June 2003

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Clymer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032015